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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,212	10/30/2003	David R. Hennings	NSL-501	2780

34313 7590 05/17/2006

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EXAMINER

SHAY, DAVID M

ART UNIT PAPER NUMBER

3735

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/699,212	HENNINGS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on February 27, 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

14-23, 25-46

- 4) ☒ Claim(s) 1-17 and 19-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2006 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

At the outset, the examiner will address the remarks drawn to the rejection of claim 14. Applicant posits that claim 14 was intended to be rejected under the combination applied to claim 1 et cetera. This is not the case. Claim 14 was intended to be rejected under the combination applied thereto.

The examiner will now address applicant's comments. Applicant relies on three articles submitted with the amended claims to bolster the assertion that it would not have been obvious to the artisan of ordinary skill to employ the highly absorbed wavelength of Dew in the method of Goldman ('084). Applicant's argument is that the authors of the articles believe that the mechanism of action of the lasers is the absorption by blood of the energy. While the articles do discuss this, it is noted that the articles also all clearly state that the ultimate cause of successful outcomes of the laser procedures is due to the heat damage of the vessel wall. This is also discussed in Goldman et al ('084) (see column 9, lines 10-12). While the articles of Proebstle et al discuss the need for blood and that saline filled veins do not provide heat distribution during laser application, these are all conclusions reached with respect to wavelengths in the 800 and 900 nanometer range. There is no discussion of the 1320 nanometer wavelength of Dew. It is

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further noted that the Min et al article, while teaching away from using the 1064 nanometer wavelength, does not discuss any other wavelengths (other than the 810 nanometer wavelength of which is the subject of the article) either pro or con. The examiner has included the reference to Sinofsky to show the knowledge in the art of the well known high absorption of wavelengths in the claimed range. While these arguments are noted with respect to the apparatus claims, they are not convincing, as an apparatus such as claimed could also be used for other purposes, such as heating prostate tissue.

The amendment filed February 27, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "delivering the beam of light adjacent to the wall of the targeted varicose vein".

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "delivering the beam of light adjacent to the wall of the targeted varicose vein".

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is indefinite as the exact meaning of the term “delivering the beam of light adjacent to the wall of the targeted varicose vein” is unclear.

a Claims 1, 2, 6, 7, 25, 35-38, 40, 41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al. Goldman et al ('084) teach a method as claimed, but do not specify a wavelength. Sinofsky teaches the notorious nature of the high absorption of infrared wavelengths in the art. Dew et al teach the desirability of using 1.3 micron radiation to treat tissue. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take its place, and since this wavelength is highly absorbed by tissue and water, as taught by Sinofsky, thus producing a method such as claimed.

Claims 3-5, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed, noting that the desired rate is dependent on the laser energy. It would have been obvious to the artisan of ordinary skill to employ a pull back as claimed, since these are known in the art and

provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is hereby taken, thus producing a method such as claimed.

Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed, it would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue, while thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing. It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ

the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber. It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

Applicant's arguments with respect to claims 1-17, 19-23, and 25-46 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David M. Shay", written in a cursive style.

DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330